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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,621	12/11/2003	Atul Varadhachary	HO-P02705US2	8531
26271 7590 06/22/2007 FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			EXAMINER KAM, CHIH MIN	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 06/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/733,621

Applicant(s)

VARADHACHARY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-22 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-7,11-17 and 20-22 is/are allowed.
- 6) ☒ Claim(s) 8-10,18,19 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1, 3-22 and 35-37 are pending.

Applicants' amendment filed on April 17, 2007 is acknowledged. Applicants' response has been fully considered. Claims 1, 8, 11-13, 15-19 and 35 have been amended, and claims 38-53 have been cancelled. Thus, claims 1, 3-22 and 35-37 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1, 3-22 and 35-53 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in view of applicant's amendment to the claim, applicants' cancellation of the claims, and applicant's response at page 5 of the amendment filed April 17, 2007.

3. The previous rejection of claims 38-53 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' cancellation of the claims, and applicant's response at page 5 of the amendment filed April 17, 2007.

Withdrawn Claim Rejections - 35 USC § 102

4. The previous rejection of claims 1, 3-6, 11, 15, 16 and 18-22 under 35 U.S.C. 102(e) as being anticipated by Ando *et al.* (US 2004/0018190), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 5-6 of the amendment filed April 17, 2007.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 19 are indefinite because of the use of the term "of lactoferrin per day". The term cited renders the claim indefinite, it is not clear how the lactoferrin composition comprises lactoferrin since the independent claim (i.e., claim 1) recites the composition comprises a N-terminal lactoferrin variant, not lactoferrin.

New Claim Rejections - 35 USC § 103

6. Claims 8-10 and 35-37 are under 35 U.S.C. 103(a) as being unpatentable over Nuuens *et al.* (WO 98/33509).

Nuuens *et al.* teach human lactoferrin (hLF) and hLF variants (e.g., N-terminal variants, hLF^{-2N}, hLF^{-3N}, hLF^{-4N}, hLF^{-5N}, lack of N-terminal Gly and Arg; page 7, line 30-page 8, line 23) can be used to treat a patient to inhibit the growth of a solid tumor (e.g., page 3, lines 1-2; page 19, lines 26-27; claims 8, 9, 35, 36); and human lactoferrin and hLF variants can be prepared in a pharmaceutical composition with a pharmaceutical carrier having the concentration of the polypeptide at least 1% to 20% by weight (pages 20, lines 10-22; claims 10 and 37). Although Nuuens *et al.* do not specifically indicate the use of lactoferrin or its N-terminal variant to treat pain, the reference does suggest using lactoferrin or its N-terminal variant to treat a patient having solid tumor. At the time of invention was made, it would have been obvious to one of ordinary skill in the art that using N-terminal lactoferrin variant to inhibit tumor growth in a patient would provide improvement in pain because the reference teaches using the same N-terminal lactoferrin variant to treat a patient suffering from pain (e.g., patients having a solid

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tumor) as the claimed method, which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

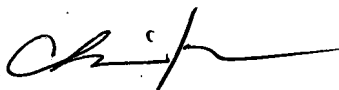
7. Claims 8-10, 18, 19 and 35-37 are rejected; and claims 1, 3-7, 11-17 and 20-22 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

June 16, 2007